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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|--|-------------|----------------------|---------------------|------------------|--|
| 10/699,208 | 10/31/2003 | Leonard Stevens | 64104-00002USPT | 2784 | |
| 7590 | 07/27/2004 | | EXAMINER | | |
| CROWE & DUNLEVY, P.C. 20 NORTH BROADWAY SUITE 1800 OKLAHOMA CITY, OK 73102-8273 | | MENDOZA, MICHAEL G | | | |
| | | ART UNIT | | PAPER NUMBER | |
| | | 3731 | | | |

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

4W

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/699,208 | STEVENS ET AL. | |
| | Examiner | Art Unit | |
| | Michael G. Mendoza | 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 24 February 2004.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-19 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-13, 15-17 and 19 is/are rejected.
 7) Claim(s) 14 and 18 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 24 February 2004 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>9 February 2004</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: 21, 31, 32, and 50. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

3. The abstract of the disclosure is objected to because undue length. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 4, 5, 6, 7, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Crossett et al. 4201215.
6. Regarding claim 1, Crossett et al. disclose in Fig. 3 the device comprising impermanently joined sliding (20) and receiving (22,26) attachment structures. Each structure has a cross member (Fig. 1: elements 24, 26), a plurality of integrated leg (Fig. 4: elements 30, 32) and foot portions (Fig. 4: elements 34, 36), a plurality of sternum engagement surfaces (all elements in Fig. 3), and an end portion (Fig. 3: elements 24, 30).
7. Regarding claims 4, 5, and 6 Crossett et al. disclose in the Abstract (lines 6-8) and in Fig. 9 the sternum engagement surfaces contact the frontal and posterior portions of a sternum. In Fig. 9, although the feet portions (Fig. 3: elements 34, 36) cannot be seen, they would be located on the posterior portion of the sternum.
8. Regarding claim 7, Crossett et al. disclose in Fig. 9 the receiving attachment structure comprising a securing means (28) to facilitate the securing of the structures to one another.
9. Regarding claim 10, Crossett et al. disclose in Fig. 9 the first (20) and second (22) attachment structures are sized and dimensioned to engage opposite sides of a sternum while positioned intercostally.

Claim Rejections - 35 USC § 103

Art Unit: 3731

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1-13, 15, 16, 17, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogendijk et al. 6051007 in view of Crossett et al. 4201215.

12. Regarding claims 1 and 2, Hogendijk et al. disclose in Fig. 12 the device comprising impermanently joined sliding (10'') and receiving (30'') attachment structures. Each structure has a cross member (see Fig. 12 inserted below) and an end portion (12''). Fig. 12 is a structurally analogous embodiment of Fig. 1 (col. 3, lines 65-67), which more clearly shows the receiving attachment structure's end portion (32) and the plurality of sternum engagement surfaces (bottom of 17 and 72, 20, 22, 40, 42). Hogendijk et al., however, disclose in Fig. 1 only one foot (20, 40) and leg (16, 36) portion on each structure and not a plurality of foot and leg portions on each structure. Crossett et al. disclose in Fig. 4 a plurality of foot (36, 38) and leg (30, 32) portions on each structure. This additional structure is simply a duplication of parts, and it is well known to add another leg or foot portion to enhance the securement of the sternum clamp to the sternum. It would have been obvious to one having ordinary skill in the art at the time of the invention to add another leg and foot portion to each structure to strengthen attachment of the device to the sternum.

13. Regarding claim 2, Hogendijk et al. disclose in Fig. 12 the receiving structure (30'') comprising a resiliently tensioned locking member with angularly disposed teeth

like structures (47) outwardly positioned at first (bottom 470) and second (top 470) ends of the locking member. Hogendijk et al. further disclose a securing aperture (440) substantially centered there between.

14. Regarding claims 1, 3-10, 12, and 15, Hogendijk et al. disclose in Fig. 9 the device comprising impermanently joined sliding (114) and receiving (134) attachment structures. Each structure has a cross member (12', 32') and an end portion (the left and right ends of 12', 32'). Fig. 1 of which Fig. 9 is a structurally analogous embodiment (col. 3, lines 54-56), shows the plurality of sternum engagement surfaces (bottom of 17 and 72, 20, 22, 40, 42). Hogendijk et al., however, disclose in Fig. 1 only one angled foot (20, 40, the foot is angle with respect to the leg) and leg (16, 36) portion on each structure and not a plurality of foot and leg portions on each structure. Crossett et al. disclose in Fig. 4 a plurality of foot (36, 38) and leg (30, 32) portions on each structure. This additional structure is simply a duplication of parts, and it is well known to add another leg or foot portion to enhance the securement of the sternum clamp to the sternum. It would have been obvious to one having ordinary skill in the art at the time of the invention to add another leg and foot portion to each structure to strengthen attachment of the device to the sternum.

15. Regarding claim 3, Hogendijk et al. disclose in Fig. 9 the sliding structure (114) comprising a plurality of projection members (see Fig. 9 below) with angularly disposed teeth like structures (152) inwardly positioned on each innermost surface of each projection member.

16. Regarding claims 4-6, Hogendijk et al. disclose the sternum engagement surface contacting the frontal and posterior portions of a sternum. The sternal clamp members of Fig. 9 are structurally identical to the clamp members in Fig. I (col. 10, lines 56-62).

The clamp members of Fig. 1 engage and grip both sternal halves (col. 4, lines 36-43), and thus it would be inherent that the clamp members contact the frontal portion of the sternum. In col. 4, lines 49-53, the foot portions of Fig. 1 engage the posterior portion.

17. Regarding claim 7, Hogendijk et al. disclose in Fig. 9 the receiving attachment structure (134) comprising a securing means (170) to facilitate the operative securing of the structures to one another. The teeth (170) of one structure engage the teeth (152) of the other structure to secure the structures to one another.

18. Regarding claims 8 and 9, Hogendijk et al. disclose the clamp members being made from a radiolucent biocompatible material (col. 4, lines 28-32).

19. Regarding claim 10, Hogendijk et al. disclose the first and second attachment structures are sized and dimensioned to engage opposite sides of a sternum (col. 6, lines 59-64). The first and second attachment structures are capable of facilitating the tilting of divided sternum plates.

20. Regarding claim 12, Hogendijk et al. disclose in Fig. 12 a method comprising positioning sliding (30'') and receiving (10'') attachment structures about a respective sternal half (col. 6, lines 59-64). The opposed sliding and receiving attachment structures can be aligned for insertion of sliding structure projection members (see Fig. 12 below) into receiving chambers (located on each side of 416) of the receiving attachment structure. Fig 1, of which Fig. 12 is a structurally analogous embodiment

(col. 3, lines 65-67), comprises positioning foot (20, 40) members of sliding and receiving structures upon the posterior section of the sternum (col. 4 lines 49-51) in a manner that is capable of angling upwardly the divided sternum halves. If the sternum halves are divided in a manner in which they are collapsed then the sliding and receiving attachment structures can angle the halves upwardly and hold them together. Hogendijk et al. further disclose in Fig. 12 removably positioning and securing the teeth like structures (416) on each end of a locking member to abut complimenting teeth (470) located on a plurality of projection members (434, 472) where the projection members are within the receiving chambers (located on each side of 416).

21. Regarding claim 13, Hogendijk et al. disclose all of the claimed structural limitations as set forth in claim 1. Therefore, the device of Hogendijk et al. if fully capable of intercostally positioned absent necessity for any secondary transfixion application or structure.

22. Regarding claims 15 and 17, Hogendijk et al. disclose in Fig. 9 the device wherein the securing means (170) may be removed to facilitate immediate device disengagement.

23. Regarding claims 16 and 19, Hogendijk et al. disclose in Fig. 2 the device comprising a scoring (54) of at least one portion of the device to allow severing thereof to facilitate immediate device disengagement when previously secured intercostally between at least two corresponding positioned rib pairs. Hogendijk et al. does not disclose the process of forming the scoring using a laser. A product-by-process claim must result in a structural difference between the claim and prior art. Therefore the

scoring (54) of Hogendijk et al. is fully capable of performing the disclosed function because the process does not result in a structural difference.

24. Regarding claims 1 and 11, Hogendijk et al. disclose in Fig. 10 the device comprising impermanently joined sliding (10") and receiving (30") attachment structures. Fig. 10 is structurally analogous to Fig. 1 (col. 3, lines 59-61), which discloses each structure having a cross member (12, 33), a plurality of sternum engagement surfaces (bottom of 17 and 72, 20, 22, 40, 42), and an end portion (19, 32). Hogendijk et al. further disclose in Fig. 1 each structure having an angled foot (20, 40, the foot is angled relative to the leg portion) and leg (16, 36) portion, but not a plurality of angled foot and leg portions. Crossett et al. disclose in Fig. 4 a plurality of foot (36, 38) and leg (30, 32) portions on each structure. This additional structure is simply a duplication of parts, and it is well known to add another leg and foot portion to enhance the securement of the sternum clamp to the sternum. It would have been obvious to one having ordinary skill in the art at the time of the invention to add another leg and angled foot portion to each structure to strengthen attachment of the device to the sternum.

25. Regarding claim 11, Hogendijk et al. disclose in Fig. 10 a screw type fastening means (220), which is inserted in to an aperture (230), to removably attach the sliding (10") and receiving (30") attachment structures.

Double Patenting

24. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11

F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

25. Claims 1, 4-10, and 12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-8 and 10 of U.S. Patent No. 6540769 in view of Hogendijk et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application is broader in some respects and adds feature in other respects. The structural limitations set forth in claims 1, 4-10, and 12 of the instant application are also claimed in the patent, e.g., first and second clamping structures adapted for intercostal positioning; each having a cross member, a plurality of integrated leg and foot portions, a plurality of sternum engagement surface, and an end portion.

The difference between claim 1 of the instant application and claim 1 of the patent is the sliding and receiving attachment structures.

Hogendijk et al. discloses sliding and receiving attachment structures.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use sliding and receiving attachment structures for quickly and easily separating the clamping structures from one another.

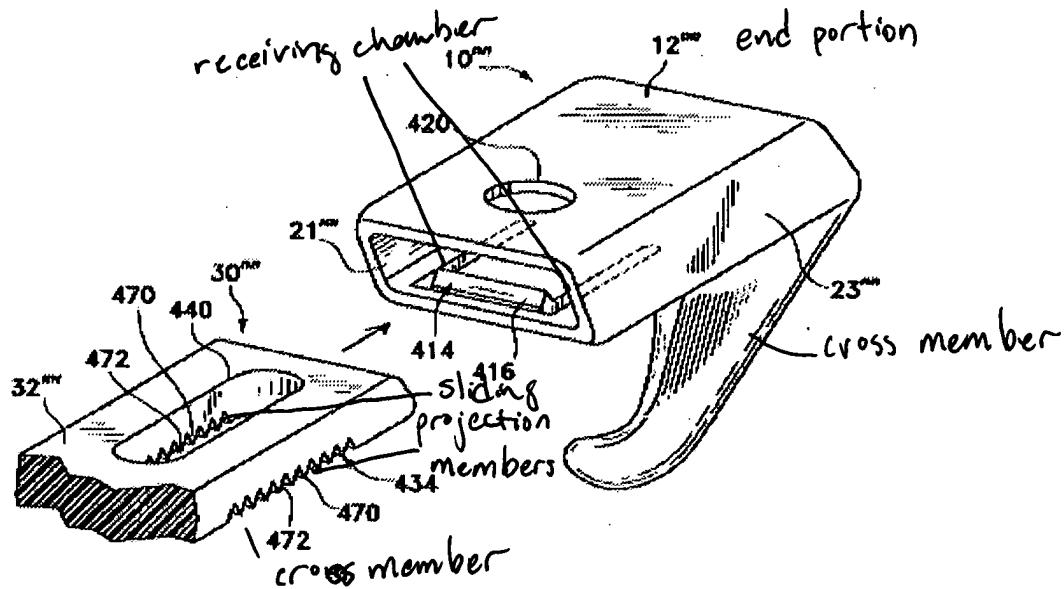
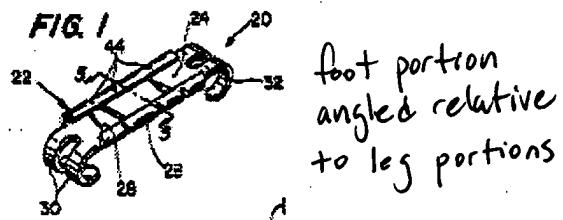


Fig. 12

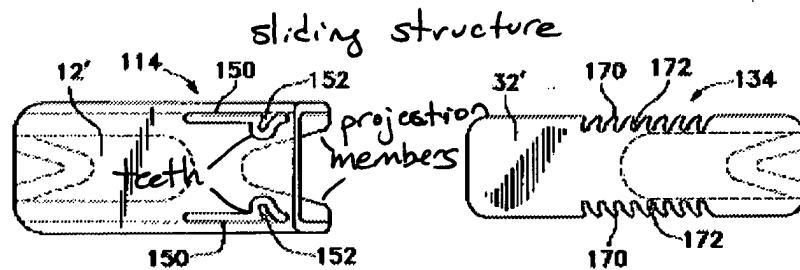


Fig. 9

Allowable Subject Matter

26. Claims 14 and 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (703) 305-3285. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Glenn Dawson can be reached on (703) 308-4304. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

MM

MM
July 23, 2004


GLENN K. DAWSON
PRIMARY EXAMINER